DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 26, 2015

Stryker Spine
Ms. Soraya King
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K142237
Trade/Device Name: Aviator® Anterior Cervical Plating (ACP) System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 29, 2014
Received: December 30, 2014

Dear Ms. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142237

Device Name
Aviator® Anterior Cervical Plating (ACP) System

Indications for Use *(Describe)*
The Stryker Spine Aviator® Anterior Cervical Plating (ACP) System is intended for use as an aid in cervical spinal fusion and is intended for unilateral fixation.

The Aviator® Anterior Cervical Plating System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

• Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
• Trauma (including fractures)
• Tumors
• Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
• Pseudoarthrosis
• Failed previous fusion
• Decompression of the spinal cord following total or partial cervical vertebrectomy
• Spondylolisthesis
• Spinal Stenosis

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) #K142237– Design Modifications to the Stryker Spine Aviator® Anterior Cervical Plate (ACP) System

Revised 510(k) Summary

510(k) Summary: Aviator® Anterior Cervical Plating (ACP) System	
Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Soraya King, MS Regulatory Affairs Specialist Phone: 201-760-8296 Fax: 201-962-4296 Email: Soraya.King@Stryker.com
Date Prepared	21 January 2015
Trade Name	Aviator® Anterior Cervical Plating (ACP) System
Common Name	Appliance, Fixation, Spinal Intervertebral Body
Proposed Class	Class II
Classification Name and Number	Spinal Intervertebral Body Fixation Orthosis 21 CFR §888.3060
Product Code	KWQ
Predicate Device	• K083562 - Stryker Spine Aviator® Anterior Cervical Plating (ACP) System, (Primary Predicate Device) • K062310, K040261 – Stryker Spine Reflex® Hybrid ACP System • K000536, K000742 – Synthes Spine Cervical Spine Locking Plate System
Device Description	The purpose of this 510(k) is to summarize the design modifications that have been implemented to the Aviator® Anterior Cervical Plating (ACP) System previously FDA cleared via K083562. No new implant reference numbers/part numbers were created. Additionally, there were no changes to the previously FDA cleared indications, intended uses, mode of operation, scientific technology, materials of construction, or to the performance of the device. The Aviator® Anterior Cervical system are one-, two-, three-, and four-level plate configurations ranging in lengths from 12 mm to 22 mm for the one-level plates, 24mm to 46mm for the two-level plates, 39 mm to 69 mm for the three-level plates, and 56 mm to 96 mm for the four-level plates. All of the plate levels incorporate a spring bar blocking mechanism to aid in prevention of bone screw back-out. The bone screws are provided with either fixed or variable angles available in self-tapping or self-drilling designs. The variable angle bone screws allow the screw to be placed into bone at various degrees of angulation, while the fixed bone screws are inserted at a defined angle. Any combination of bone screws can be used to secure

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510(k) Summary: Aviator® Anterior Cervical Plating (ACP) System	
	the cervical plate. The bone screws are offered in 4.0 mm and 4.35 mm diameters in lengths of 10 mm – 20 mm. The implants (bone screws and cervical plates) are provided as single-use, non-sterile devices manufactured from implantable grade titanium alloy (TI6Al4V). The associated instrumentation (such as awls, punch awls, screwdrivers, handles, drill guides and drill bits, plate bender, storage and transport trays/container, and fixation pins) are Class I / 510(k) exempt devices under 21 CFR §888.4540.
Indications for Use	The Stryker Spine Aviator® Anterior Cervical Plating (ACP) System is intended for use as an aid in cervical spinal fusion and is intended for unilateral fixation. The Aviator® Anterior Cervical Plating System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications: • Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies) • Trauma (including fractures) • Tumors • Deformities or curvatures (including kyphosis, lordosis, or scoliosis) • Pseudoarthrosis • Failed previous fusion • Decompression of the spinal cord following total or partial cervical vertebrectomy • Spondylolisthesis • Spinal Stenosis
Summary of the Technological Characteristics	The design modifications did not alter the fundamental scientific technology or change/introduce an energy source. The modified devices retained previously FDA cleared indications/intended use and mode of operation as presented in 510(k) #K083562. The Aviator® plates utilize the same anti-backout spring bar mechanism as the predicate design. The spring bar continues to automatically close when the screw has completely advanced through the screw slots on the plates. The design feature that allows the surgeon to rotate the blocker for additional visual and tactile feedback to ensure that the spring bars is in the secured position has been maintained. There were no changes in the materials of construction. The implants continue to be manufactured from surgical grade implantable titanium alloy.

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	The implemented design modifications did not raise new questions of safety or efficacy.
Summary of the Performance Data	Cadaveric and bench design verification testing was conducted on the modified devices to assess impact. All previous ASTM testing submitted with K083562 were repeated for the modified device: • ASTM 1717-09, "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model" o for Static Compression Bending, Dynamic (Fatigue) Compression Bending, and Static Torsion Tests • ASTM 1798-97, "Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants o for Static Cantilever Bending There were no new failure modes, identification of new risks, or establishment of a new worst-case construct as a result of the design changes. The non-clinical test results were comparable to the predicate design and demonstrated that implemented modifications did not adversely impact device performance, and the safety and effectiveness profile of the device.

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510(k) Summary: Aviator® Anterior Cervical Plating (ACP) System

Feature	Aviator® ACP System (K083562)	Modified Aviator® ACP System (Letter to File Changes)
Locking mechanism	• Spring-loaded • Spring Bar is provided pre-assembled to the plate	• Spring-Loaded • Spring Bar is provided pre-assembled to the plate
Anti-backout mechanism	Opens with screw	Opens with screw
Integrated with plate using slot to house mechanism	Integrated with plate using slot to house mechanism	Integrated with plate using slot to house mechanism
Thickness of anti-backout mechanism	.3-.4 mm	.3-.4 mm
Material	Ti 6AL-4V	Ti 6AL-4V
Number of screw holes mechanism supports	1 screw hole	1 screw hole
Basic Plate Shape	"Dogbone" design with graft viewing windows	"Dogbone" design with graft viewing windows
Plate Levels	One-, Two-, Three-, and Four- level configurations	One-, Two-, Three-, and Four- level configurations
Plate Lengths	One-level: 12-22mm Two-level: 24-46mm Three-level: 39-69mm Four-level: 56-96mm	One-level: 12-22mm Two-level: 24-46mm Three-level: 39-69mm Four-level: 56-96mm
Plate Width	17.4mm	17.4mm
Plate Profile	2.5mm thickness, smooth surface (no protrusions)	2.5mm thickness, smooth surface (no protrusions)
Plate Curvature	Sagittal – 190mm (1 & 2 level) & 390mm (3 & 4 level) Axial – 25mm	Sagittal – 190mm (1 & 2 level) & 390mm (3 & 4 level) Axial – 25mm
Plate Screw-Hole Geometry	Middle screw holes – round End screw holes – elongated	Middle screw holes – round End screw holes – elongated
Bone Screw Diameter	4.0mm and 4.35mm	4.0mm and 4.35mm

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Mechanical Performance	Tested as per ASTM 1717 and ASTM 1798	Tested as per ASTM 1717 and ASTM 1798
Conclusions	The modified device has identical indications, technological characteristics, and principles of operation as the predicate design. The non-clinical test data demonstrated that the implemented design changes did not impact the performance of the device, the function of the device, or how the device is utilized in comparison to the predicate design. There were no new risks identified associated with the implemented changes. The modifications have demonstrated to be substantially equivalent to the previously cleared design and predicate systems presented in 510(k) #K083562.	